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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,011	07/11/2001	Avi Ashkenazi	10466/45	1120

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/26/2003

1f

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/904,011

Applicant(s)
ASHKENAZI et al.

Examiner
Christine Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7,9 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Claims 1-38 have been canceled and claims 39-44 have been added as requested in the amendment of paper #1.5, filed 11 July 2001. Claims 39 and 44 have been amended as requested by Applicant in paper #14, filed 28 October 2002. Claims 39-44 are pending in the instant application.

Priority

2. Applicant has amended the priority claim in the first line of the specification in paper #12, filed 27 August 2002.

3. According to the priority statement of 27 August 2002, it appears that the claimed subject matter defined in the instant application is supported by PCT application PCT/US00/04414 filed 2/22/2000. Based on the invention given by Applicant and an inspection of the parent applications, the Examiner has concluded that the subject matter defined in this application is supported by the disclosure PCT/US00/04414, filed 2/22/2000 but is not supported by any of the other applications because the claimed subject matter does not have utility/enablement. The use of the claimed invention for inhibition of VEGF stimulated proliferation of adrenal cortical capillary endothelial cells is first taught in PCT/US00/04414, and this is found to have utility and is enabled by the specification as filed. However, PCT/US98/19437, filed 9/17/1998 does not

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teach this utility, and therefore, priority is not granted to this application. Accordingly, the subject matter defined in claims 39-44 has an effective filing date of 2/22/2000.

Should the Applicant disagree with the Examiner's factual determination above, it is incumbent upon the Applicant to provide the serial number and specific page number(s) of any parent application filed prior to 2/22/2000 which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which Applicant considers to have been in possession of and fully enabled for prior to 2/22/2000.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 124, line 37. The specification should be carefully reviewed for any other occurrences of hyperlinks. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Double Patenting

5. Applicant is advised that should claim 39 be found allowable, claim 44 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a

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substantial duplicate of the allowed claim. See MPEP § 706.03(k). See also the 112/2nd rejection for the limitation “specifically” binds below.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 39 and 44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 39 and 44 are directed to an antibody that binds to the polypeptide of SEQ ID NO:4, an such an antibody could exist in nature. The rejection would be obviated by the insertion of the word “isolated” in front of “antibody”.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 42 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is indefinite because an antibody cannot be both an antibody and an antibody fragment.

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Claim 44 is indefinite because it is not clear what “specifically” binds means. Though this term is used in the specification, it is not defined. Further, it is not clear how this limitation distinguishes the antibody of claim 44 from that of claim 39. How much more does the antibody of claim 44 bind to the protein such that it is different from the antibody of claim 39? The metes and bounds of “specifically” are not clear and the claim is indefinite.

art rejection over antibodies.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 39 and 44 are rejected under 35 U.S.C. 102(a) as being anticipated by HSIEH et al. (Nature 398: 431-436, 1999).

HSIEH et al. disclose an isolated polypeptide which has 99.7% amino acid sequence identity to the amino acid sequence of the polypeptide shown in Figure 4 (SEQ ID NO:4). See

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Figure 1. The single difference in amino acid sequence between the polypeptide of SEQ ID NO:4 recited in the instant claims and the polypeptide of HSIEH et al. occurs at position 178.

Specifically, the amino acid at position 178 in SEQ ID NO:4 of the instant application is glutamine, whereas the amino acid at position 178 of HSIEH et al. is leucine. However, HSIEH et al. teach production of antibodies to amino acids 29-168, which are identical to the disclosed protein (see page 435, column 2, under Methods). Therefore, the antibodies of HSIEH anticipate claims 39 and 44.

12. Claims 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by BREWER et al. (WO 98/54963; published 10 December 1998).

BREWER et al. teach a polypeptide (SEQ ID NO:426) which has approximately 99% amino acid sequence identity with the disclosed polypeptide of SEQ ID NO:4. The differences between the disclosed polypeptide and the polypeptide of BREWER et al. are found at positions 264, 300 and 380. Positions 264 and 300 are indicated to be Xaa, which is a wildcard amino acid. See pages 579-580 of BREWER et al. The reference is 772 pages in length, and therefore, will not be provided in this Office action unless Applicant specifically requests the entire document. BREWER et al. further disclose an isolated antibody which specifically binds to the polypeptide (SEQ ID NO:426) (page 221 of BREWER et al.) as well as methods of production which teach monoclonal antibodies, protein binding fragments thereof, and humanized antibodies (see pages 237-238 of BREWER et al.). Therefore, BREWER et al. anticipates the instant claims.

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It is noted that there are 3 differences between the protein of BREWER et al. (SEQ ID NO:426) and the disclosed protein of SEQ ID NO:4. However, antibodies raised to the protein of SEQ ID NO:426 of BREWER et al. would specifically bind the protein of the disclosed SEQ ID NO:4 due to the 99% amino acid sequence identity. Epitopes for antibody binding can be as short as 6 amino acids, and vast majority, if not all generated antibodies to SEQ ID NO:426 would be expected to bind to SEQ ID NO:4, and therefore, the antibodies of BREWER et al. anticipate the instant claims.

The differences between the disclosed polypeptide and the polypeptide of BREWER et al. are found at positions 264, 300 and 380. Positions 264 and 300 are indicated to be Xaa, which is a wildcard amino acid. Frequently in the biotech. arts, amino acid sequence analysis fails to reliably provide each and every amino acid in a protein sequence. This is sometimes due to disulfide bonds between cysteine residues. Therefore, the amino acids at these positions may very well be cysteine residues (inherent to the polypeptide of BREWER et al), which would be the same as the disclosed protein since the residues at these positions in SEQ ID NO:4 are cysteine residues. With regard to inherency, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, *the applicant has the burden of showing that they are not* (emphasis added)." *In re Spada*, 15 USPQ2d 1655, 1658 (Fed. Cir.

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1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 195 USPQ 430, 433 (CCPA 1977). *In re Papesch*, 315 F.2d 381, 137 USPQ 42, 51 (CCPA 1963) held that "From the standpoint of patent law, a compound and all its properties are inseparable." It is noted that the protein of BREWER et al. has an extra amino acid at position 380, however, the instant claims recite "comprising", which encompasses additional amino acids.

Conclusion

13. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud